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CONFIRMATION NO. APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. R. Sanders Williams 2337 09/782,953 02/13/2001 UTSD:674US/SLH **EXAMINER** 7590 06/02/2004 Steven L. Highlander LIU, SAMUEL W Fulbright & Jaworski L.L.P. PAPER NUMBER ART UNIT Suite 2400 600 Congress Avenue 1653 Austin, TX 78701 DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)
	09/782,953	WILLIAMS ET AL.
	Examiner	Art Unit
	Samuel W Liu	1653
The MAILING DATE of this communication appears on the cover sheet with the correspondence address		
THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.		
PERIOD FOR REPLY [check either a) or b)]		
 a) The period for reply expiresmonths from the mailing date of the final rejection. b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). 		
Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
1. A Notice of Appeal was filed on Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.		
2. The proposed amendment(s) will not be entered because:		
(a) They raise new issues that would require further consideration and/or search (see NOTE below);		
(b) ☑ they raise the issue of new matter (see Note below);		
(c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or		
(d) They present additional claims without canceling a corresponding number of finally rejected claims.		
NOTE: See Continuation Sheet.		
3. Applicant's reply has overcome the following rejection(s):		
4. Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).		
5.⊠ The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.		
6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.		
7. For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.		
The status of the claim(s) is (or will be) as follows:		
Claim(s) allowed: <u>none</u> .		
Claim(s) objected to: <u>none</u> .		
Claim(s) rejected: <u>59,61,62 and 70</u> .		
Claim(s) withdrawn from consideration: <u>none</u> .		
8. The drawing correction filed on is a) approved or b) disapproved by the Examiner.		
9. Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s)		
10. Other:		
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Continuation of 2. NOTE: The claim rejection under 35 U.S.C. 112, first paragraph, is maintained, because the claim recitations "selecting ..." (claim 59) and "human subject" (claims 59 and 70) introduce new matter into the claims; these recitations represent a departure from the specification and the claims as originally filed, and are not supported by the specification. Thus, the recitations change the scope of the instant disclosure as filed, and introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Continuation of 5, does NOT place the application in condition for allowance because: The rejection to claims 59, 61-62 and 70 under 35 U.S.C. 112, second paragraph is maintained. Claim 59 recitation "modulation" is unclear as to whether or not the modulation refers to upor down-regulation. The dependent claims are included in the rejection. As indicated in Office action mailed 28 January 2003 (see page 3), one substance (modulator) cannot act as an agonist meanwhile as an antagonist. Thus, the method that is directed to use of such substance (modulator) has to be clarified as to which mechanism, agonist mechanism (up-regulation) or antagonist mechanism (downregulation), the claimed method is directed. Therefore, agonist (claim 61) and antagonist (claim 62) need to be also clarified.

KAREN COCHRANE CARLSON, PH.D.

PRIMARY EXAMINER

Javer Cahane Carlson